

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

BOSTON SCIENTIFIC CORPORATION;
BOSTON SCIENTIFIC SCIMED, INC;
BOSTON SCIENTIFIC LIMITED; and
ENDOVASCULAR TECHNOLOGIES, INC.

Plaintiffs,

v.

COOK, INC; WILSON-COOK MEDICAL,
INC.; COOK MEDICAL INC.; COOK
IRELAND LTD.; COOK GROUP, INC.;
TAEWOONG MEDICAL CO., LTD;
STANDARD SCI-TECH INC.;
ENDOCHOICE, INC.; and SEWOON
MEDICAL CO. LTD.

Defendants.

Civil Action No. 1:10-cv-11646-DPW

JURY TRIAL DEMANDED

**ANSWER AND COUNTERCLAIMS OF
DEFENDANT COOK MEDICAL INCORPORATED**

Defendant Cook Medical Incorporated ("Cook Medical") hereby answers the First Amended Complaint ("Complaint") of Plaintiffs Boston Scientific Corporation ("BSC"), Boston Scientific Scimed, Inc. ("BSSI"), Boston Scientific Limited ("BSL"), and Endovascular Technologies, Inc. ("ETI") (collectively "Plaintiffs") as follows:

ANSWER

NATURE OF ACTION

1. Cook Medical denies that it has infringed, or is infringing, any valid claim of United States Patent Nos. 6,007,574 ("the '574 Patent"), 6,309,415 ("the '415 Patent"), 7,160,323 ("the '323 Patent"), 7,419,502 ("the '502 Patent"), 7,419,503 ("the '503 Patent"), 7,736,386 ("the '386

Patent"), 7,763,068 ("the '068 Patent"), 6,533,810 ("the '810 Patent"), 6,818,015 ("the '015 Patent"), and 5,876,448 ("the '448 Patent"). Cook Medical admits that the Complaint purports to allege patent infringement against Cook Medical and the other Defendants, but denies any remaining allegations set forth in paragraph 1 of the Complaint.

PARTIES

Plaintiffs

2. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint and therefore denies them.

3. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint and therefore denies them.

4. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Complaint and therefore denies them.

5. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 5 of the Complaint and therefore denies them.

Cook Defendants

6. Cook Medical admits that Cook Incorporated (also known as Cook, Inc.) is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, Bloomington, Indiana 47404, but denies any remaining allegations set forth in paragraph 6 of the Complaint.

7. Cook Medical admits the allegations of paragraph 7.

8. Cook Medical admits that Cook Medical Incorporated is a corporation organized under the laws of Indiana and has a principal place of business in Bloomington Indiana, but denies any remaining allegations set forth in paragraph 8 of the Complaint.

9. Cook Medical admits the allegations of paragraph 9.

10. Cook Medical admits that Cook Group Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, Bloomington, Indiana 47904, but denies any remaining allegations of paragraph 10 of the Complaint.

11. Cook Medical admits that it makes, uses, sells, offers for sale, or imports into the U.S. endoscopy products for treatment of diseases of the digestive system, including but not limited to stents and related delivery systems. Cook Medical admits that it uses, sells, and offers for sale the EVOLUTION® stent and delivery device in the U.S. Cook Medical denies that it makes the EVOLUTION® stent and delivery device. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 11 of the Complaint and therefore denies them.

Taewoong Defendant

12. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 12 of the Complaint and therefore denies them.

13. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 13 of the Complaint and therefore denies them.

Standard Sci-Tech Defendants

14. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 14 of the Complaint and therefore denies them.

15. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 15 of the Complaint and therefore denies them.

16. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 16 of the Complaint and therefore denies them.

17. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in Paragraph 17 of the Complaint and therefore denies them.

JURISDICTION AND VENUE

18. Cook Medical admits that the Complaint purports to state an action for patent infringement arising under the patent laws of the United States. Cook Medical admits that the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies any remaining allegations of paragraph 18 of the Complaint.

19. Cook Medical admits only for the purposes of this action that this Court has personal jurisdiction over Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 19 of the Complaint and therefore denies them.

20. Cook Medical admits that venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and/or 1400(b) as to Cook Medical. Cook Medical denies that a substantial part of the events giving rise to the claims in the complaint occurred in this district. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 20 of the Complaint and therefore denies them.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,007,574

21. Cook Medical incorporates by reference its responses to paragraphs 1-20 of the Complaint as if fully set forth herein.

22. Cook Medical admits that the face of U.S. Patent No. 6,007,574 is entitled "Stent," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '574 Patent lists the issue date as December 28, 1999. Cook

Medical denies that the Patent Office duly and legally issued the '574 Patent as well as any remaining allegations set forth in paragraph 22 of the Complaint.

23. Cook Medical denies the allegations of paragraph 23 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 23 of the Complaint and therefore denies them.

24. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint and therefore denies them.

25. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint and therefore denies them.

26. Cook Medical denies the allegations of paragraph 26 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 26 of the Complaint and therefore denies them.

27. Cook Medical denies the allegations of paragraph 27 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 27 of the Complaint and therefore denies them.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 6,309,415

28. Cook Medical incorporates by reference its responses to paragraphs 1-27 of the Complaint as if fully set forth herein.

29. Cook Medical admits that the face of U.S. Patent No. 6,309,415 is entitled "Stent," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '415 Patent lists the issue date as October 30, 2001. Cook

Medical denies that the Patent Office duly and legally issued the '415 Patent as well as any remaining allegations set forth in paragraph 29 of the Complaint.

30. Cook Medical denies the allegations of paragraph 30 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 30 of the Complaint and therefore denies them.

31. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 31 of the Complaint and therefore denies them.

32. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 32 of the Complaint and therefore denies them.

33. Cook Medical denies the allegations of paragraph 33 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 33 of the Complaint and therefore denies them.

34. Cook Medical denies the allegations of paragraph 34 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 34 of the Complaint and therefore denies them.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,160,323

35. Cook Medical incorporates by reference its responses to paragraphs 1-34 of the Complaint as if fully set forth herein.

36. Cook Medical admits that the face of U.S. Patent No. 7,160,323 is entitled "Method of Reconstructing Body Lumens," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '323 Patent lists the issue

date as January 9, 2007. Cook Medical denies that the Patent Office duly and legally issued the '323 Patent as well as any remaining allegations set forth in paragraph 36 of the Complaint.

37. Cook Medical denies the allegations of paragraph 37 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 37 of the Complaint and therefore denies them.

38. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 38 of the Complaint and therefore denies them.

39. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 39 of the Complaint and therefore denies them.

40. Cook Medical denies the allegations of paragraph 40 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 40 of the Complaint and therefore denies them.

41. Cook Medical denies the allegations of paragraph 41 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 41 of the Complaint and therefore denies them.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 7,419,502

42. Cook Medical incorporates by reference its responses to paragraphs 1-41 of the Complaint as if fully set forth herein.

43. Cook Medical admits that the face of U.S. Patent No. 7,419,502 is entitled "Stent," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '502 Patent lists the issue date as September 2, 2008. Cook

Medical denies that the Patent Office duly and legally issued the '502 Patent as well as any remaining allegations set forth in paragraph 43 of the Complaint.

44. Cook Medical denies the allegations of paragraph 44 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 44 of the Complaint and therefore denies them.

45. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 45 of the Complaint and therefore denies them.

46. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 46 of the Complaint and therefore denies them.

47. Cook Medical denies the allegations of paragraph 47 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 47 of the Complaint and therefore denies them.

48. Cook Medical denies the allegations of paragraph 48 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 48 of the Complaint and therefore denies them.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 7,419,503

49. Cook Medical incorporates by reference its responses to paragraphs 1-48 of the Complaint as if fully set forth herein.

50. Cook Medical admits that the face of U.S. Patent No. 7,419,503 is entitled "Stent," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '503 Patent lists the issue date as September 2, 2008. Cook

Medical denies that the Patent Office duly and legally issued the '503 Patent as well as any remaining allegations set forth in paragraph 50 of the Complaint.

51. Cook Medical denies the allegations of paragraph 51 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 51 of the Complaint and therefore denies them.

52. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 52 of the Complaint and therefore denies them.

53. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 53 of the Complaint and therefore denies them.

54. Cook Medical denies the allegations of paragraph 54 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 54 of the Complaint and therefore denies them.

55. Cook Medical denies the allegations of paragraph 55 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 55 of the Complaint and therefore denies them.

COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 7,736,386

56. Cook Medical incorporates by reference its responses to paragraphs 1-55 of the Complaint as if fully set forth herein.

57. Cook Medical admits that the face of U.S. Patent No. 7,736,386 is entitled "Stent," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '386 Patent lists the issue date as June 15, 2010. Cook

Medical denies that the Patent Office duly and legally issued the '386 Patent as well as any remaining allegations set forth in paragraph 57 of the Complaint.

58. Cook Medical denies the allegations of paragraph 58 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 58 of the Complaint and therefore denies them.

59. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 59 of the Complaint and therefore denies them.

60. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 60 of the Complaint and therefore denies them.

61. Cook Medical denies the allegations of paragraph 61 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 61 of the Complaint and therefore denies them.

62. Cook Medical denies the allegations of paragraph 62 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 62 of the Complaint and therefore denies them.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 7,763,068

63. Cook Medical incorporates by reference its responses to paragraphs 1-62 of the Complaint as if fully set forth herein.

64. Cook Medical admits that the face of U.S. Patent No. 7,763,068 is entitled "Stent," and purports to name S.A. Pulnev, A.V. Karev, and S.V. Schukin as the inventors. Cook Medical admits that the face of the '068 Patent lists the issue date as July 27, 2010. Cook

Medical denies that the Patent Office duly and legally issued the '068 Patent as well as any remaining allegations set forth in paragraph 64 of the Complaint.

65. Cook Medical denies the allegations of paragraph 65 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 65 of the Complaint and therefore denies them.

66. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 66 of the Complaint and therefore denies them.

67. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 67 of the Complaint and therefore denies them.

68. Cook Medical denies the allegations of paragraph 68 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 68 of the Complaint and therefore denies them.

69. Cook Medical denies the allegations of paragraph 69 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 69 of the Complaint and therefore denies them.

COUNT VIII: INFRINGEMENT OF U.S. PATENT NO. 6,533,810

70. Cook Medical incorporates by reference its responses to paragraphs 1-69 of the Complaint as if fully set forth herein.

71. Cook Medical admits that the face of U.S. Patent No. 6,533,810 is entitled "Conical Stent," and purports to name S. Hankh, M. Gianotti, and E. Hofmann as the inventors. Cook Medical admits that the face of the '810 Patent lists the issue date as March 18, 2003. Cook

Medical denies that the Patent Office duly and legally issued the '810 Patent as well as any remaining allegations set forth in paragraph 71 of the Complaint.

72. Cook Medical denies the allegations of paragraph 72 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 72 of the Complaint and therefore denies them.

73. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 73 of the Complaint and therefore denies them.

74. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 74 of the Complaint and therefore denies them.

75. Cook Medical denies the allegations of paragraph 75 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 75 of the Complaint and therefore denies them.

76. Cook Medical denies the allegations of paragraph 76 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 76 of the Complaint and therefore denies them.

COUNT IX: INFRINGEMENT OF U.S. PATENT NO. 6,818,015

77. Cook Medical fully incorporates its responses to paragraphs 1-76 of the Complaint as if fully set forth herein.

78. Cook Medical admits that the face of U.S. Patent No. 6,818,015 is entitled "Conical Stent," and purports to name S. Hankh, M. Gianotti, and E. Hofmann as the inventors. Cook Medical admits that the face of the '015 Patent lists the issue date as November 16, 2004. Cook

Medical denies that the Patent Office duly and legally issued the '015 Patent as well as any remaining allegations set forth in paragraph 78 of the Complaint.

79. Cook Medical denies the allegations of paragraph 79 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 79 of the Complaint and therefore denies them.

80. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 80 of the Complaint and therefore denies them.

81. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the allegations set forth in paragraph 81 of the Complaint and therefore denies them.

82. Cook Medical denies the allegations of paragraph 82 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 82 of the Complaint and therefore denies them.

83. Cook Medical denies the allegations of paragraph 83 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 83 of the Complaint and therefore denies them.

COUNT X: INFRINGEMENT OF U.S. PATENT NO. 5,876,448

84. Cook Medical incorporates by reference its responses to paragraphs 1-83 of the Complaint as if fully set forth herein.

85. Cook Medical admits that the face of U.S. Patent No. 5,876,448 is entitled "Esophageal Stent," and purports to name R.J. Thompson, J.E. Laptewicz, Jr., and P.J. Thompson as the inventors. Cook Medical admits that the face of the '448 Patent lists the issue

date as March 2, 1999. Cook Medical denies that the Patent Office duly and legally issued the '448 Patent as well as any remaining allegations set forth in paragraph 85 of the Complaint.

86. Cook Medical denies the allegations of paragraph 86 as to Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 86 of the Complaint and therefore denies them.

87. Cook Medical denies the allegations of paragraph 87 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 87 of the Complaint and therefore denies them.

88. Cook Medical denies the allegations of paragraph 88 as to the results of any actions of Cook Medical. Cook Medical is without sufficient information or knowledge to form a belief as to the truth of the remaining allegations set forth in paragraph 88 of the Complaint and therefore denies them.

PRAYER FOR RELIEF

Cook Medical denies that Plaintiffs are entitled to any relief, specifically denies each allegation and request for relief in paragraphs (a) through (e) of Plaintiffs' Prayer for Relief, and prays for judgment in favor of Cook Medical dismissing this action and awarding Cook Medical its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs in this action, and any further relief that this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without altering the burden of proof, Cook Medical asserts the following defenses.

FIRST DEFENSE

(Failure to State a Claim)

89. The First Amended Complaint fails to state a claim against Cook Medical upon which relief may be granted.

SECOND DEFENSE

(Noninfringement)

90. Cook Medical does not infringe and has not infringed, either directly or indirectly, does not and has not induced infringement, and does not and has not contributed to the infringement of any claim of the '448 Patent, the '574 Patent, the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, the '068 Patent, the '810 Patent, or the '015 Patent (collectively "the Patents-in-Suit"), literally or under the doctrine of equivalents.

THIRD DEFENSE

(Invalidity)

91. The claims of the Patents-in-Suit are invalid or unenforceable for failure to comply with one or more provisions of Title 35 of the U.S. Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

FOURTH DEFENSE

(Prosecution History Estoppel)

92. Cook Medical alleges that the claims of the Patents-In-Suit are and were limited by amendment, by the prior art, and/or by the statements made during their prosecution before the U.S. Patent & Trademarks Office, such that Plaintiffs are now estopped and otherwise precluded from maintaining that such claims are of sufficient scope to cover the accused products, either literally or under the doctrine of equivalents.

FIFTH DEFENSE

(Unenforceability)

93. One or more claims of the Patents-In-Suit are unenforceable. All of the claims of the '574 Patent, the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent are unenforceable due to inequitable conduct and/or unclean hands, including the acts and failures to act set forth in Cook Medical's Third Counterclaim for a Declaration of Unenforceability for Inequitable Conduct alleged below, which is incorporated by reference into this affirmative defense.

SIXTH AFFIRMATIVE DEFENSE

(35 U.S.C. § 287)

94. Cook Medical alleges that any claim for damages by Plaintiffs for patent infringement is limited by 35 U.S.C. § 287 to only those damages occurring after proper notice of infringement to Cook Medical.

SEVENTH AFFIRMATIVE DEFENSE

(Laches)

95. Cook Medical alleges that Plaintiffs' claims are barred by the doctrine of laches.

RESERVATION OF DEFENSES

96. To the extent not already pled, Cook Medical reserves its right to add additional defenses pending further investigation and discovery.

PRAYER FOR RELIEF

WHEREFORE, Cook Medical prays for relief as follows:

A. That the Court enter judgment in favor of Cook Medical and against Plaintiffs on each of the claims in Plaintiff's Complaint;

- B. That Plaintiffs' claims be dismissed in their entirety, with prejudice;
- C. That Plaintiffs take nothing by way of their claims;
- D. That this case is determined exceptional within the meaning of 35 U.S.C. § 285;
- E. That Cook Medical be awarded its costs of suit, including attorneys' fees, incurred in defense of this action; and
- F. That the Court award Cook Medical other such relief as is just and proper.

COUNTERCLAIMS BY COOK MEDICAL

For its counterclaims against Plaintiffs BSC, BSSI, BSL, and ETI (collectively "Counterclaim Defendants"), Defendant and Counterclaimant Cook Medical ("Counterclaimant") states as follows:

NATURE OF THIS ACTION

1. This is an action for declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* On September 27, 2010, Counterclaim Defendants filed an action against Counterclaimant and other Defendants Cook Incorporated, Wilson-Cook Medical Inc., Cook Group Incorporated, Cook Ireland Ltd., Taewoong Medical Co., Ltd., Standard Sci-Tech Inc., Endochoice, Inc., and Sewoon Medical Co., Ltd. (collectively "Defendants") alleging infringement of United States Patent No. 5,876,448 ("the '448 Patent"), United States Patent No. 6,007,574 ("the '574 Patent"), United States Patent No. 6,533,810 ("the '810 Patent"), and United States Patent No. 6,818,015 ("the '015 Patent"). On December 2, 2010, Plaintiffs filed a First Amended Complaint against Counterclaimant and the other Defendants that additionally alleged infringement of U.S. Patent No. 6,309,415 ("the '415 Patent"), U.S. Patent No. 7,160,323 ("the '323 Patent"), U.S. Patent No. 7,419,502 ("the '502 Patent"), U.S. Patent No. 7,419,503 ("the '503 Patent"), U.S. 7,736,386

("the '386 Patent"), and U.S. Patent No. 7,763,068 ("the '068 Patent"), and maintained the previously named '448 Patent, the '574 Patent, the '810 Patent, and the '015 Patent (collectively "the Patents-in-Suit"). Counterclaimant denies infringing any valid claims of the Patents-in-Suit.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of these counterclaim pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

3. This Court has personal jurisdiction over Counterclaim Defendants at least by virtue of their submission to the jurisdiction of this Court.

4. To the extent that venue for the underlying Complaint is proper, venue in this judicial district for this counterclaim is proper under 28 U.S.C. §§ 1391(b) and/or 1391(c).

PARTIES

5. Counterclaimant Cook Medical Incorporated ("Cook Medical") is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, Bloomington, Indiana 47404.

6. Counterclaim Defendant Boston Scientific Corporation ("BSC") alleges that it is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 1 Boston Scientific Pl., Natick, MA 01760. BSC alleges that it is the owner by assignment of the '810 Patent and the '015 Patent.

7. Counterclaim Defendant Boston Scientific SciMed Inc. ("BSSI") alleges that it is a corporation organized and existing under the laws of the state of Minnesota with a principal place of business at One Scimed Place, Maple Grove, MN 55311. BSSI purports to be a wholly owned subsidiary of BSC. BSSI alleges that it is the owner by assignment of the '448 Patent.

8. Counterclaim Defendant Boston Scientific Limited ("BSL") alleges that it is a corporation organized and existing under the laws of Ireland with a principal place of business at Ballybrit Business Park, Galway, Ireland. BSL purports to be a wholly owned subsidiary of BSC, and BSL alleges that it is an exclusive licensee of the '574 Patent, the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent.

9. Counterclaim Defendant Endovascular Technologies Inc. ("EVT") alleges that it is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 4100 Hamline Avenue North, St. Paul, MN 55112. EVT purports to be a wholly owned subsidiary of BSC, and ETI alleges that it is the owner by assignment of the '574 Patent, the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent.

FIRST COUNTERCLAIM

(Declaratory Judgment of Invalidity)

10. Counterclaimant realleges paragraphs 1 through 9 of these Counterclaims as if set forth fully herein.

11. A genuine dispute has arisen between Counterclaimant and Counterclaim Defendants as to the validity of the Patents-in-Suit, asserted by Counterclaim Defendants against Counterclaimant.

12. Counterclaimant seeks a judicial determination that the Patents-in-Suit are invalid by reason of failure to satisfy the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112 as well as any other bases for invalidity.

SECOND COUNTERCLAIM

(Declaratory Judgment of Non-infringement)

13. Counterclaimant realleges paragraphs 1 through 12 of these Counterclaims as if set forth fully herein.

14. A genuine dispute has arisen between Counterclaimant and Counterclaim Defendants as to whether any action by Counterclaimant infringes any claim of the Patents-in-Suit, asserted by Counterclaim Defendants against Counterclaimant.

15. Counterclaimant seeks a judicial determination that no action taken in the past or currently being taken constitutes infringement of any claim of the Patents-in-Suit.

THIRD COUNTERCLAIM

(Declaratory Judgment of Unenforceability for Inequitable Conduct)

16. Counterclaimant realleges paragraphs 1 through 15 of these Counterclaims as if set forth fully herein.

17. Counterclaimant seeks a judicial determination that at least the '574 Patent, the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent are unenforceable because the applicants and/or their attorneys acted with inequitable conduct and/or unclean hands during prosecution of the applications that matured into each of the patents named above. Counterclaimant reserves the right to supplement this Third Counterclaim to add additional facts regarding the actions taken (or not taken) during prosecution of the applications that matured into the Patents-in-Suit that are later discovered by Counterclaimant during discovery.

18. On information and belief, while prosecuting the application that matured into the '574 Patent (U.S. Application No. 08/860,462 ("the '462 application")), the named inventors in

the application and/or their agents, attorneys, and assigns (collectively, "Applicants") engaged in conduct before the United States Patent and Trademark Office ("USPTO") that renders the '574 Patent as well as the children thereof (the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent) unenforceable. Specifically, the application that matured into the '574 Patent claimed priority to PCT/RU94/00292, filed on December 23, 1994 ("the PCT application" attached as Exhibit A), which claimed priority to Russian Patent application No. 93058166, filed on December 28, 1993 ("the Russian application" attached as Exhibit B). Upon information and belief, the named inventors on the '574 Patent (S.A. Pulnev, A.V. Karev, and S.V. Schukin) were also named as inventors in each of the Russian and PCT applications and, upon information and belief, the Russian and PCT applications were filed solely in the name of the three named inventors.

There is a well-known statutory 30-month deadline for nationalizing a PCT application with the USPTO. 35 U.S.C. §371(b). This 30-month deadline is measured from an application's earliest claimed priority date, which in the case of the '462 application is the Russian application filing date of December 28, 1993. The steps necessary to meet this statutory deadline, which in this case was June 28, 1996, were not taken. Instead, the Applicants, by way of their attorney J. Bennett Mullinax, submitted application papers almost one year after the statutory deadline, on June 27, 1997, claiming priority from the PCT application, a purported English translation of the PCT application, an application fee, and a paper styled "Petition for Revival of the Application under 37 C.F.R. §1.137(b)." ("the Petition" attached as Exhibit C.) In the Petition, the Applicants requested the USPTO to revive the patent application despite the Applicants' failure to take the necessary steps by the June 28, 1996 statutory deadline to nationalize the PCT application in the USPTO. In the Petition, Mr. Mullinax stated: "The delay to prosecute said

application was unintentional. Abandonment occurred for failure to timely enter the U.S.

National Phase of PCT prosecution by 28 June 1996. This Petition is filed within one year of the date on which the application became abandoned." (*See* Petition, Exhibit C.)

Upon review of the filed application papers and the Petition, on November 24, 1997, the USPTO's petition reviewing officer (P. F. Kratz) dismissed the Petition without prejudice due to an inadequacy with the English translation document submitted with the application papers filed on June 27, 1997. In response, Mr. Mullinax filed a paper styled "Renewed Petition Under 37 C.F.R. § 1.137(b)" on January 22, 1998 which included a purportedly proper English translation of the PCT application. On May 11, 1998, the USPTO petition reviewing officer granted the Applicants' Petition to revive the application, and the USPTO thereafter recognized Applicants' claim for priority to the PCT and Russian applications. (*See* USPTO papers attached as Exhibit D.)

Upon information and belief, Mr. Mullinax's June 1997 statement, that the failure to take the necessary steps by the June 28, 1996 PCT 30-month nationalization deadline was "unintentional," was a knowingly false statement made to mislead the USPTO and the USPTO's petitions officer. Upon information and belief, Mr. Mullinax's statement that the delay in prosecuting the application (*i.e.* the delay in filing the materials necessary to nationalize the PCT application until almost one year after the June 28, 1996 deadline) was "unintentional," was made in an attempt to satisfy the USPTO's requirements under the "Unintentionally Abandoned" standard for reviving the abandoned application. (*See* 37 C.F.R. 1.137(b), recited in Manual of Patent Examining Procedure 711.03(c) (6th ed., rev. 2, (June 1996)), attached as Exhibit E.)

The Applicants' failure to take the necessary steps to nationalize the PCT application before the statutory 30-month deadline could not have been unintentional for several reasons.

First, the executed Declaration submitted with the application papers on June 27, 1997, was purportedly executed by each named inventor well before the expiration of the PCT 30-month nationalization deadline on June 28, 1996. (Declaration submitted with '462 application attached as Exhibit F.) Specifically, named inventor S.A. Pulnev purportedly executed the submitted Declaration on June 14, 1996, named inventor A.V. Karev purportedly executed the submitted Declaration on June 14, 1996, and named inventor S.V. Schukin purportedly executed the submitted Declaration on June 6, 1996. Because the Declaration is specifically configured for United States patent practice and specifically configured to claim priority to the PCT and Russian applications, and dated well before the statutory deadline, the most reasonable conclusion is that the Applicants were acting knowingly and deliberately with respect to attempting to secure United States patent rights. When the Applicants' attorney prepared the Declaration for the named inventors' signatures, and when the named inventors purportedly signed the Declaration, the Applicants undoubtedly intended to file a U.S. national phase PCT application claiming priority to the PCT application within the PCT 30-month deadline of June 28, 1996. Because all of these actions took place well before the June 28, 1996 statutory deadline, there must have been intent to file an U.S. national phase PCT application before the statutory June 28, 1996 deadline, and therefore Mr. Mullinax's statement to the contrary in the Petition of June 1997 -- that the delay to prosecute the U.S. national phase PCT application was "unintentional" -- cannot be accurate.

Second, the Applicants filed a European national phase application (EP Application No. 95905819.9 "the EPO application") with the European Patent Office ("EPO"), through their European counsel, D.H. Stringer of W.P. Thompson & Co., on July 24, 1996. The EPO application was filed within the EPO's requirement of filing an EPO national stage PCT

application no later than 31 months from the earliest priority date, *i.e.* by July 28, 1996. (EPO application papers attached as Exhibit G.) Like in the United States, the EPO application claimed priority to the PCT application, which ultimately claimed priority to the Russian application. The Applicants' filing of the EPO application, by way of their European counsel, provides additional evidence that the Applicants and their various patent counsel were aware of the world-wide PCT nationalization régimes, and the required filing deadlines at least in the United States and Europe, and were actively and deliberately considering whether to file in the United States and Europe in June and July, 1996.

The Applicants' June 1997 claim, through their U.S. patent attorney Mr. Mullinax, that the delay to prosecute the application that became the '462 application (including the failure to timely enter the U.S. National Phase of PCT prosecution by June 28, 1996) was somehow "unintentional," cannot be accurate based upon this evidence. On the contrary, the Applicants' and their attorney's acts described above speak directly to the Applicants' awareness (including that the Declaration was prepared by their attorney and purportedly executed by the named inventors) of the applicable statutory filing deadline.

In view of this evidence, Mr. Mullinax's after-the-fact statement of an alleged "unintentional" delay in the Petition, submitted on June 27, 1997, was made with the intent to deceive the USPTO and the USPTO's petitions officer in order to obtain a granted Petition and thereby revive the application that had become abandoned for failure to meet the statutory deadline. This statement is also highly material to patentability at least based upon the Applicants' claim for priority to the PCT application and the Russian application. Because the PCT application published on July 6, 1995, the PCT application would have been anticipatory prior art to the '462 application under 35 U.S.C. § 102(b) (having published more than one year

prior to the belated actual filing date of the '462 application) if the '462 application is not given the benefit of a priority claim to the PCT application. Without the priority claim, at least claim 1 of the '574 Patent, among other claims in the associated patent family, would not have been allowed to issue because the disclosure in the published PCT application is the purported basis for the claimed subject matter.

Accordingly, there is significant evidence that Mr. Mullinax's statement in the Petition was false, was made with specific intent to mislead and deceive the USPTO and the USPTO petitions officer so as to revive the abandoned application, and this was highly material to patentability. Thus, the Applicants, at least by way of Mr. Mullinax, acted with inequitable conduct and the '574 Patent that resulted from the '462 application and its associated family claiming priority therefrom, including the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent, should be rendered unenforceable.

DEMAND FOR JUDGMENT

WHEREFORE, Cook Medical prays for judgment as follows:

- A. That judgment be entered declaring that the claims of the Patents-in-Suit are invalid;
- B. That judgment be entered declaring that the claims of the Patents-in-Suit are not infringed by Cook Medical;
- C. That judgment be entered declaring the unenforceability of at least the '574 Patent, the '415 Patent, the '323 Patent, the '502 Patent, the '503 Patent, the '386 Patent, and the '068 Patent;
- D. That this case be declared exceptional within the meaning of 35 U.S.C. § 285;
- E. That Cook Medical be awarded its costs of suit, including attorneys' fees, incurred in defense of this action; and

F. That the Court award Cook Medical other such relief as is just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, Cook Medical hereby demands trial by jury of all issues so triable by a jury in this action, including claims and counterclaims.

Dated: January 7, 2011

Respectfully Submitted,

/s/ Matthew N. Kane

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document filed through the ECF system will be sent electronically to the registered participants as identified in the Notice of Electronic filing (NEF) and paper copies will be sent to those indicated as nonregistered participants on January 7, 2011.

/s/ Matthew N. Kane
Matthew N. Kane

Dated: January 7, 2011